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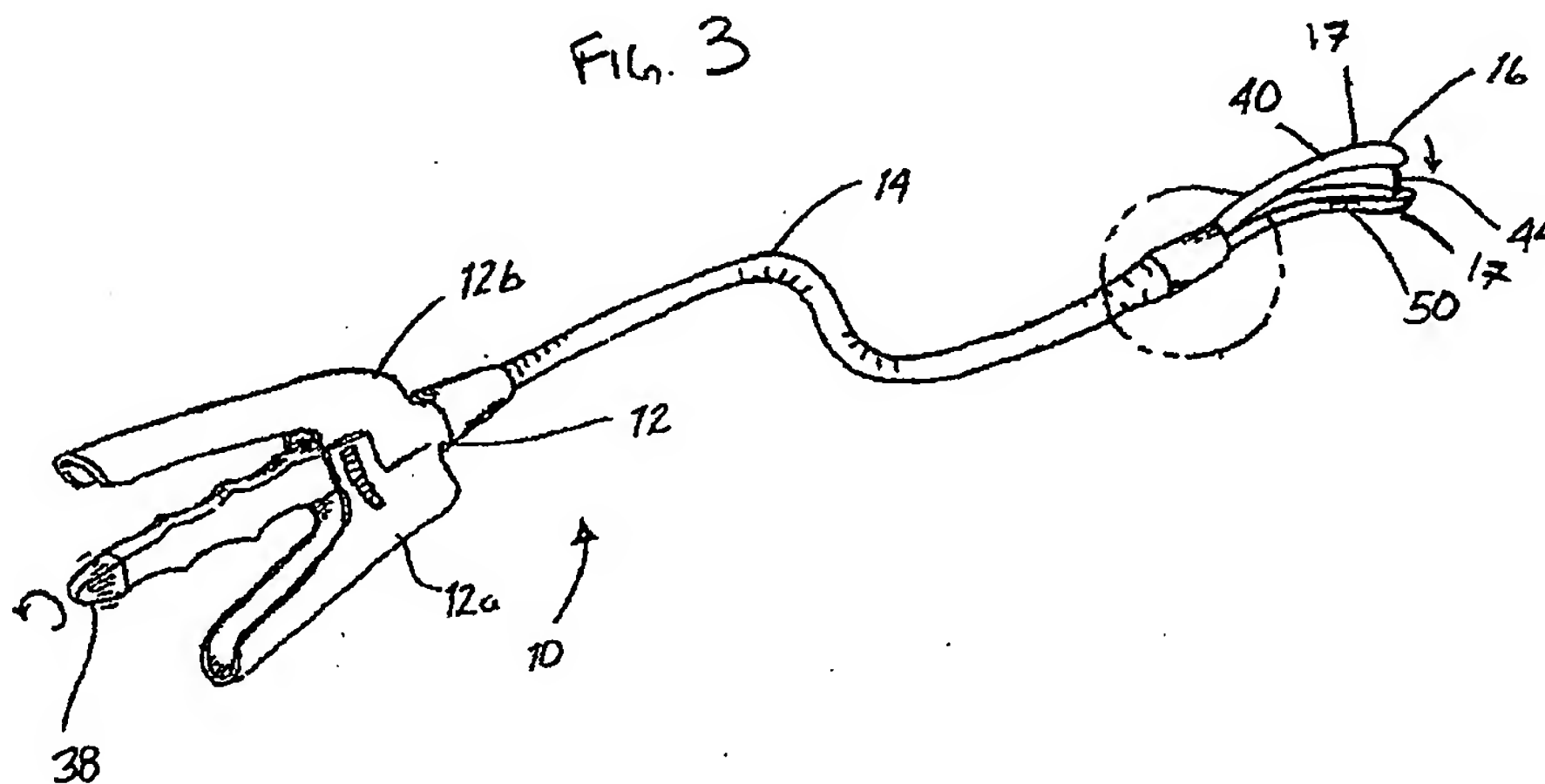
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(54) Title: APPARATUS AND METHOD FOR STAPLING AND RESECTIONING GASTRO-ESOPHAGEAL TISSUE



(57) Abstract: A system for stapling tissue comprises a flexible endoscope (20) and an operative head including a pair of opposed, curved tissue clamping jaws (17) sized to pass through an esophagus, the jaws (17) being moveable with respect to one another between an open tissue receiving configuration and a closed tissue clamping configuration, a first one of the curved jaws (17) including a stapling mechanism (40) and a second one of the jaws (17) including a staple forming anvil surface (50A), the stapling mechanism including staple slots through which staples are fired arranged in a row extending from a proximal end of the first jaw to a distal end thereof in combination with a control handle (12) which, when the operative head is in an operative position within one of a patient's stomach and esophagus, remains outside the patient, the control handle including a first actuator (12A) for moving the jaws relative to one another and a second actuator (12B) for operating the stapling mechanism.

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APPARATUS AND METHOD FOR STAPLING AND RESECTIONING GASTRO-ESOPHAGEAL TISSUE

Field Of The Invention

[0001] The present invention relates to endoscopic devices for performing localized resections of gastro-esophageal lesions.

Background of the Invention

[0002] Endoscopic surgical stapling apparatus are known in the art and are utilized to provide a variety of surgical procedures. For example, U.S. Patent No. 5,040,715 to Green, et al. discloses an endoscopic stapling device configured to be inserted through a small entrance wound in the abdominal cavity to place rows of staples in body tissue. This device has a limited range of motion in that the stapling assembly at the distal end of the instrument can only be rotated about the central axis of the instrument.

[0003] An endoscopic stapling apparatus purporting to have a greater range of motion is disclosed in U.S. Patent No. 5,326,013 to Green et al. This device has an articulating stapling assembly mounted for pivotal movement about an axis extending transverse to the central axis of the instrument. An endoscopic stapling device designed to be inserted through a small incision in a body wall and purporting to have an increased range of motion is described in U.S. Patent No. 5,389,098 to Tsuruta et al. A stapling assembly of this device curves away from a central axis of the instrument to a 90° angle so that it can more easily reach tissue spaced from the central axis. This device

incises tissue clamped within the stapling assembly and places staggered lines of staples on both sides of the incision.

Summary Of The Invention

[0004] The present invention is directed to a system for stapling tissue comprising a flexible endoscope and an operative head including a pair of opposed, curved tissue clamping jaws sized to pass through an esophagus, the jaws being moveable with respect to one another between an open tissue receiving configuration and a closed tissue clamping configuration, a first one of the curved jaws including a stapling mechanism and a second one of the jaws including a staple forming anvil surface, the stapling mechanism including staple slots through which staples are fired arranged in a row extending from a proximal end of the first jaw to a distal end thereof in combination with a control handle which, when the operative head is in an operative position within one of a patient's stomach and esophagus, remains outside the patient, the control handle including a first actuator for moving the jaws relative to one another and a second actuator for operating the stapling mechanism.

Brief Description Of The Drawings

[0005] Fig. 1 shows a perspective view of a system according to an illustrative embodiment of the present invention along with a partially cross-sectional view of a patient showing a target portion of tissue to be resected;

Fig. 2a shows the system of Fig. 1 inserted into the patient's body via the mouth;

Fig. 2b shows a display of the image of a stapling apparatus of the system of Fig. 1 provided to a user;

Fig. 2c shows a cross-sectional view of the patient's esophagus with the stapling apparatus of Fig. 3 in position adjacent to the target portion of tissue;

Fig. 3 shows a perspective view of the system of Fig. 1 with jaws of the stapling apparatus open;

Fig. 4 shows a partially cross-sectional view of a proximal end of the stapling apparatus of Fig. 3 showing control cables for operating the jaws configured as when the jaws are open;

Fig. 5 shows a perspective view of the system of Fig. 1 with jaws of the stapling apparatus closed with a lower actuator lever on a control handle being actuated;

Fig. 6 shows a partially cross-sectional view of the control handle of the system of Fig. 5 showing a coupling between control cables for operating the jaws and the lower actuator lever on the control handle;

Fig. 7 shows a partially cross-sectional view of a proximal end of the stapling apparatus of Fig. 5 showing control cables for operating a stapling pusher of the stapling apparatus configured as when the lower actuator lever is actuated;

Fig. 8 shows a perspective view of the system of Fig. 1 with jaws of the stapling apparatus closed with an upper actuator lever on the control handle being actuated;

Fig. 9 shows a partially cross-sectional view of a portion of the control handle of the system of Fig. 8 showing a coupling between control cables for operating the jaws and the upper actuator lever on the control handle;

Fig. 10 shows a partially cross-sectional view of a proximal end of the stapling apparatus of Fig. 5 showing control cables for operating a stapling pusher of the stapling apparatus configured as when the upper actuator lever is actuated;

Fig. 11 shows a partially cross-sectional view of a stapling assembly of the system of Fig. 1 grasping esophageal tissue;

Fig. 12 shows a partially cross-sectional view of the stapling assembly of the system of Fig. 1 illustrating a mechanism for grossly approximating the jaws of the stapling assembly;

Fig. 13 shows a partially cross-sectional view of the stapling assembly illustrating a mechanism for finely approximating the jaws in an initial position;

Fig. 14 shows a perspective view of an I-beam member of the fine approximation mechanism of Fig. 13;

Fig. 15 shows a partially cross-sectional view of the stapling assembly with the fine approximation mechanism in a partially advanced position;

Fig. 16 shows a perspective view of the stapling assembly with a C-shaped clamp member thereof in an initial

position;

Fig. 17 shows a perspective view of the C-shaped clamp member of Fig. 16 rotated 180° removed from the jaws;

Fig. 18 shows a cross-sectional view of the stapling assembly with the C-shaped clamp member in a partially advanced position;

Fig. 19 shows an alternate embodiment of the system according to the present invention with a lateral endoscope receiving lumen;

Fig. 20 shows the system of Fig. 19 with an endoscope received therein;

Fig. 21 shows a system in accord with the present invention positioned within the stomach to perform a procedure for the treatment of reflux; and

Fig. 22 shows a system in accord with the present invention positioned within the stomach to perform a stomach reduction procedure.

Detailed Description

[0006] A detailed description of illustrative embodiments of the present invention is provided in conjunction with the attached drawings. In the descriptions of the various embodiments and the corresponding drawings, like reference numerals refer to like elements.

[0007] A method and apparatus for resectioning

anastomized luminal tissue is disclosed in U.S. Patent No. 5,868,760 to McGuckin et al., the disclosure of which is hereby incorporated by reference in its entirety. The disclosed apparatus includes a flexible tubular body and a distal operating capsule that may be inserted through either a naturally occurring body orifice or a surgical incision and guided to an operative site endoscopically or using radiologic imaging guidance. In use the target tissue is stapled, cut and captured within the operating capsule for removal from the body. The healthy tissue is thereby anastomized by surgical staples.

[0008] Fig. 1 shows a system for resecting esophageal tissue according to an illustrative embodiment of the present invention. A surgical stapling apparatus, designated generally by the reference numeral 10, is utilized in conjunction with an endoscope 20 for providing remote vision of an operative area and to assist in guiding the stapling apparatus 10 to the operative area. An endoscopic grasping device 30 extends through a lumen in the endoscope 20 for use at the surgical site as would be understood by those of skill in the art. Those skilled in the art will further understand that, while the illustrative embodiments are described in conjunction with visual observation of the operative site via the endoscope 20, these procedures may also be visualized through the use of Magnetic Resonance Imaging (MRI). In this case, components of the system and the instruments utilized therewith, such as the grasping device 30, would be constructed from non-ferrous material such as titanium, as would be understood by those of skill in the art.

[0009] As shown in Fig. 1, the stapling apparatus 10

includes a proximal handle portion 12, an elongated flexible body portion 14 extending from the handle portion 12 and a generally C-shaped stapling assembly 16 operatively associated with a distal end of the flexible body portion 14. The flexible body portion 14 and the stapling assembly 16 are preferably dimensioned and configured to traverse the natural curvature of the esophagus. As shown in Figs. 2b and 2c and described in detail below, the stapling assembly 16 includes a pair of opposable jaws 17 defined by a staple carrying portion 40 and a staple forming portion 50. Those skilled in the art will understand that, although the jaws 17 are described herein as rotating relative to one another between the open and closed positions, that these jaws 17 may be coupled by a mechanism which allows them to move linearly with respect to one another or in any other manner so long as they move between a first position in which the jaws 17 are separated from one another to receive tissue and a second position in which the jaws 17 are clamped together to hold tissue tightly therebetween for stapling.

[0010] Furthermore, those skilled in the art will understand that the system may operate with any of a variety of commercially available medical endoscopes which may include, for example, a proximal handle portion 22, an elongated flexible body portion 24 through which one or more interior lumina extend for accommodating, for example, a fiber optic bundle or other image transmission structure, a working channel for the grasping device 30, etc. Those skilled in the art will understand that the fiber optic bundle (or other image transmitting structure) allows a user to remotely visually monitor a field of view at the distal end of the endoscope (e.g., an operative site S within the esophagus E). As would be further understood by those of

skill in the art, the tissue grasping device 30 may include a handle portion 32, an elongated flexible body portion 34 and a pair of opposable jaws 36a and 36b.

[0011] In use as shown in Figs. 2a - 2c, the surgical stapling apparatus 10 and the flexible endoscope 20 are introduced into a patient's mouth and advanced into the esophagus to the operative site S under visual guidance from the endoscope 20. Once at the site S, the operator maneuvers the stapling assembly 16 into a desired position relative to the tissue to be resected (how is this maneuvering done?). The jaws 17 of the stapling assembly 16 are then opened to a tissue receiving position as shown in Fig. 3 and the grasping device 30 is advanced from the distal end of the endoscope 20. The jaws 36a and 36b are rotated away from one another by manipulation of the grasper handle portion 32 and the tissue T to be resected is grasped by closing the jaws 36a, 36b. The grasping device 30 is then withdrawn into the working channel of the endoscope 20 to pull the tissue T into position between the jaws 17 of the stapling assembly 16 and the jaws 17 are closed to clamp the tissue T in place between the staple carrying portion 40 and the staple forming portion 50. Those skilled in the art will understand that the tissue T is preferably drawn between the jaws 17 so that a margin of healthy tissue is positioned between the staple carrying portion 40 and the staple forming portion 50 to ensure that all of the diseased or damaged tissue T is removed. Those skilled in the art will understand that this may be visually confirmed through the use of the vision system of the endoscope as shown in Fig. 2b.

[0012] As shown in Fig. 2c, once the tissue T has been

properly positioned between the jaws 17, the jaws 17 are grossly approximated and are then finely approximated using a translating clamping member 60, illustrated in detail in Figs. 16 - 18. As shown in Figs. 3, 4 and 12, an illustrative embodiment of the system according to the present invention includes an actuation cable 44 to facilitate gross approximation of the jaws 17 via actuation of an actuator knob 38. The actuation cable 44 may be secured to the one of the jaws 17 including, for example, the staple carrying portion 40 and is operatively coupled to the other jaw 17 including the staple forming portion 50 by a member 85 which may, for example, be a spindle, capstan or other member around which the cable 44 passes to change direction to generate the clamping force to draw the jaws 17 together. Furthermore, an overhanging flange 98 at a proximal end of the staple carrying portion 40 acts as a tissue shield preventing the target tissue T from entering into the joint between the jaws 17.

[0013] As shown in Figs. 3 - 7, to actuate the clamping member 60 to finely approximate the jaws 17, the lower clamping handle 12a is actuated in the direction of the arrow in Fig. 5 to cause the integral gear rack 62a to turn pinion gear 62b which rotates elongated drive cable 64. As shown in Fig. 7, the drive cable 64 is coupled to a drive screw 63 so that rotation of the drive cable 64 rotates the drive screw 63 moving the clamping member 60 distally as shown in Fig. 18. This finely approximates the jaws 17 of the stapling assembly 16 whereby a tissue contacting surface of the staple carrying portion 40 and a tissue contacting surface of the staple forming portion 50 are brought into cooperative alignment, tightly clamping the tissue therebetween. Those skilled in the art will understand that

alternative sources of power (e.g., electrical, hydraulic, pneumatic, etc.) may be applied to drive the jaws 17 and to drive all other mechanisms of the stapling assembly 16.

[0014] As shown in Fig. 8, once the jaws 17 have been brought into cooperative alignment with one another, the stapling assembly 16 may be actuated to fire staples through the clamped tissue while simultaneously cutting away the tissue T from the stapled and anastomized tissue. The user actuates the stapling assembly 16 to drive staples through the margin of healthy tissue in one or more arcuate bands located radially outward of a line of tissue cutting. Alternatively, those skilled in the art will understand that the stapling operation may be separated from the tissue cutting operation so that no tissue is cut until the entire stapling operation has been successfully concluded.

[0015] Specifically, as shown in Figs. 8 - 10, the operator drives an I-beam member 70 through the stapling assembly 16 by operating the clamping handle 12b in the direction of the arrow in Fig. 8, causing gear rack 72a to rotate pinion gear 72b which rotates a staple driving drive cable 74 as shown in Fig. 9. The drive cable extends through the flexible body portion 14 to a linear drive screw 76 which drives a flexible pusher 80 coupled to the I-beam member 70 as shown in Fig. 10.

[0016] As shown in Figs. 11, 13, 14 and 15, the I-beam member 70 includes upper and lower beam portions 82a, 82b, respectively, connected by a central web portion 84. A leading edge 84a of the central web portion 84 may preferably define a cutting blade for incising tissue as the I-beam member 70 is moved distally as described below. As

shown in Fig. 11, an arcuate channel 90 within which the central web portion 84 travels, is defined in the opposing jaws 17 radially inward of the arcuate lines of staple carrying slots (not shown). Those skilled in the art will understand that the staple slots may be arranged in any number of rows, for example, from one to five such rows may be included and the slots of these rows may be staggered so that to ensure that the opening created by the resection is completely sealed.

[0017] As described above, actuation of the lower handle 12a causes the C-shaped clamp member 60 to move along an arc the length of the curved stapling assembly 16 to finely approximate the jaws 17 toward one another. As shown in Figs. 13, 14 and 15, the clamp member 60 includes a body portion 112 from which depend upper and lower clamping beams 114a and 114b, respectively, for urging the jaws 17 toward one another.

[0018] In addition, as shown in Figs. 16 and 17, in one embodiment of the invention, the body 112 includes a radially depending driving stem 115 having a sloped leading edge configured to extend through an arcuate slot 116 formed in the staple carrying portion 40 for sequentially contacting each of a plurality of staple pushers 118. The staple pushers 118 are positioned so that, when contacted by the driving stem 115, each staple pusher 118 is driven through a corresponding one of the staple slots to drive a staple housed therein from the slot out of the staple carrying portion 40, through both thicknesses of the folded portion of tissue clamped between the jaws 17 and against the staple forming surface 50a of the staple forming portion 50 to couple the two thicknesses of tissue to one another.

In this embodiment, the clamping member 60 further includes an integral cutting blade 130 for forming an arcuate incision substantially concentric with and radially within an inner one of the arcs of staple slots. Furthermore, the cutting blade 130 is preferably positioned so that it trails the leading edge 115 so that tissue is stapled before it is cut.

[0019] As shown in Fig. 15, according to a further embodiment of the invention, actuation of the upper actuation handle 12b causes the I-beam member 70 to move through the stapling assembly 16 to sequentially fire arcuate rows of staples while simultaneously cutting tissue away from the esophagus radially within the rows of staples. When the I-beam member 70 is driven by the pusher 80, the sloped leading edge of the upper beam portion 82a contacts sequentially each of a plurality of staple pushers 118 to drive them through their respective staple slots to drive the staples housed therein from each slot out of the staple carrying portion 40, through both thicknesses of the folded portion of tissue clamped between the jaws 17 and into the staple forming pockets 122 formed in the staple forming surface 50a of the staple forming portion 50 to couple the two thicknesses of tissue to one another. As the leading edge 84a of the central web portion 84 is proximal to the sloped leading edge, the incision trails the stapling action so that only tissue within the arc that has previously been stapled is severed.

[0020] As shown in Figs. 19 and 20, according to a further embodiment of the invention, a stapling assembly 16' according to the present invention may include an endoscope receiving lumen 140 through which the endoscope 20 may be

slidably inserted. This allows an operator to use to steering and vision capability of the endoscope 20 to locate the operative site S. Once the distal end of the endoscope 20 is positioned adjacent to the site S, the stapling assembly 16' may be slid along the endoscope 20 to the operative site S and the steering capability of the distal end of the endoscope 20 may be employed to achieve a desired position and orientation of the stapling assembly 16' relative to the tissue T. Other than the endoscope receiving lumen 140, the construction of the rest of the system of Figs. 19 and 20 may be substantially in accord with that of any of the previously described embodiments.

[0021] Furthermore, as shown in Figs. 21 and 22, the system according to the present invention may also be used to perform resections within the stomach. For example, the stapling apparatus 10 may be used to correct gastro-esophageal reflux ("GERD") or to perform a stomach reduction procedure. Specifically, as shown in Fig. 21, a system according to the invention may be inserted through the esophagus into a patient's stomach and the operator may position the jaws 17 under visual control via the endoscope 20 adjacent to a junction between the esophagus and the stomach. The operator then uses the steering capability of the endoscope 20, received within the endoscope lumen 140 to direct the jaws 17 toward a portion of stomach tissue to be fastened to the esophagus. Specifically, the operator grasps a portion of the stomach using the grasping device 30 and urges the tissue T toward the esophagus to create a fold of tissue with an outside surface of the stomach tissue adjacent to or in contact with an outer surface of the esophagus. This fold is then clamped by the jaws 17 and stapled together to... (how does this treat GERD - is this a

fundoplication with wrapping of the fundus around the esophagus? Is tissue resected? More details please - are any structural changes to the device required?).

[0022] Similarly as shown in Fig. 22, to perform a stomach reduction, an operator inserts a system according to the present invention into the stomach via the esophagus as described above in regard to Fig. 21 and locates a portion of tissue to be folded over on itself to reduce the size of the stomach. This tissue T is grasped by the grasping device 30 and drawn between the jaws 17 which clamp the tissue T together folded onto itself and staples the fold together. Those skilled in the art will understand that, for a stomach reduction procedure, the folded tissue radially within the staples may, if desired, be left in place without resection so that the operation may be reversed at a later date. Thus, for such a stomach reduction procedure where the folded, stapled tissue will be left in place within the stomach, the stapling apparatus 10 need not include a tissue cutting mechanism. Rather, the stapling apparatus 10 need only include structure for approximating the jaws 17 and for driving staples through the gripped fold of tissue. In this case, the C-shaped clamp member 60 would be constructed without the cutting blade 130.

[0023] The above described embodiments are for purposes of illustration only and the various modifications of these embodiments which will be apparent are considered to be within the scope of the teachings of this invention which is to be limited only by the claims appended hereto.

What Is Claimed Is:

1. A system for stapling tissue comprising:

an operative head including a pair of opposed, curved tissue clamping jaws sized to pass through an esophagus, the jaws being moveable with respect to one another between an open tissue receiving configuration and a closed tissue clamping configuration, a first one of the curved jaws including a stapling mechanism and a second one of the jaws including a staple forming anvil surface, the stapling mechanism including staple slots through which staples are fired arranged in a row extending from a proximal end of the first jaw to a distal end thereof; and

a control handle which, when the operative head is in an operative position within one of a patient's stomach and esophagus, remains outside the patient, the control handle including a first actuator for moving the jaws relative to one another and a second actuator for operating the stapling mechanism.

2. The system according to claim 1, further comprising a tissue cutting mechanism for severing from the patient's body tissue located radially within the row of staples.

3. The system according to claim 1, further comprising a staple pusher mounted for movement within the first jaw along a path substantially parallel to the row of staples.

4. The system according to claim 3, wherein the stapling mechanism fires staples in a plurality of substantially parallel rows.

5. The system according to claim 3, further comprising a tissue cutting mechanism for severing from the patient's body tissue located radially within the row of staples wherein the tissue cutting mechanism comprises a blade coupled to the staple pusher.

6. The system according to claim 1, wherein the operative head further includes a first jaw moving mechanism for gross adjustment of the position of the jaws relative to one another and a second jaw moving mechanism for fine adjustment of the jaws relative to one another.

7. The system according to claim 6, wherein the second jaw moving mechanism includes a substantially C-shaped clamp received around the first and second jaws.

8. The system according to claim 7, wherein the substantially C-shaped clamp includes a tissue cutting blade integrally formed therewith.

9. The system according to claim 6, wherein the first jaw includes a curved cam slot substantially parallel to the row of staples and wherein the substantially C-shaped clamp includes a cam follower riding within the cam slot.

10. The system according to claim 9, wherein the staple pusher is coupled to the C-shaped clamp for movement therewith.

11. The system according to claim 10, wherein the stapling mechanism includes a plurality of staple driving members, each staple driving member being received within a respective staple slot and wherein the staple pusher includes an angled surface which, when the staple pusher is driven along the path substantially parallel to the row of staples, the angled surface sequentially contacts the staple pushers to drive the staples out of the first jaw toward the second jaw.

12. The system according to claim 11, wherein the tissue cutting blade is coupled to the C-shaped clamp so that, as the stapling mechanism is operated, it trails the angled surface of the staple pusher so that tissue is cut only after a corresponding radially outer portion of tissue has been stapled.

13. The system according to claim 6, wherein the second jaw moving mechanism includes an I-beam member a web of which extends through corresponding slots in the first and second jaws with a first portion of the I-beam member being received within the first jaw and a second portion of the I-beam member being received within the second jaw.

14. The system according to claim 13, wherein the I-beam member serves as the staple pusher and wherein a first portion of the I-beam member includes a camming surface which sequentially contacts each of a plurality of staple pushers as the I-beam member is moved through the corresponding slots in the first and second jaws.

15. The system according to claim 13, wherein the I-beam member includes a tissue cutting blade extending from

the web between the first and second portions of the I-beam member.

16. The system according to claim 1, wherein the gross adjustment mechanism includes a cable extending between the control handle and the operative head, wherein the cable extends around a pivot member coupled to one of the first and second jaws to couple to the other of the first and second jaws.

17. A method for stapling tissue comprising the steps of:

inserting into a patient's mouth a flexible endoscope device including an operative head having a pair of opposed, curved tissue clamping jaws, a first one of the curved jaws including a stapling mechanism and a second one of the jaws including a staple forming anvil surface;

moving the jaws relative to one another from a closed position to an open tissue receiving position;

drawing a folded, full-thickness portion of tissue from one of the patient's stomach and esophagus between the jaws;

moving the jaws from the open position to the closed position to clamp the tissue between staple slots formed in the first jaw through which staples are fired by the stapling mechanism and the staple forming surface, wherein the staple slots are arranged in a row extending from a proximal end of the first jaw to a

distal end thereof; and

actuating the stapling mechanism to drive staples out of the staple slots through the tissue and against the staple forming surface to couple the folds of tissue to one another.

18. The method according to claim 17, wherein the tissue is located in the patient's stomach and the folds of tissue are coupled to one another to reduce a size of an interior space of the stomach.

19. The method according to claim 18, wherein tissue radially within the row of staples is left in place.

20. The method according to claim 17, wherein tissue radially within the row of staples is severed from the stapled tissue.

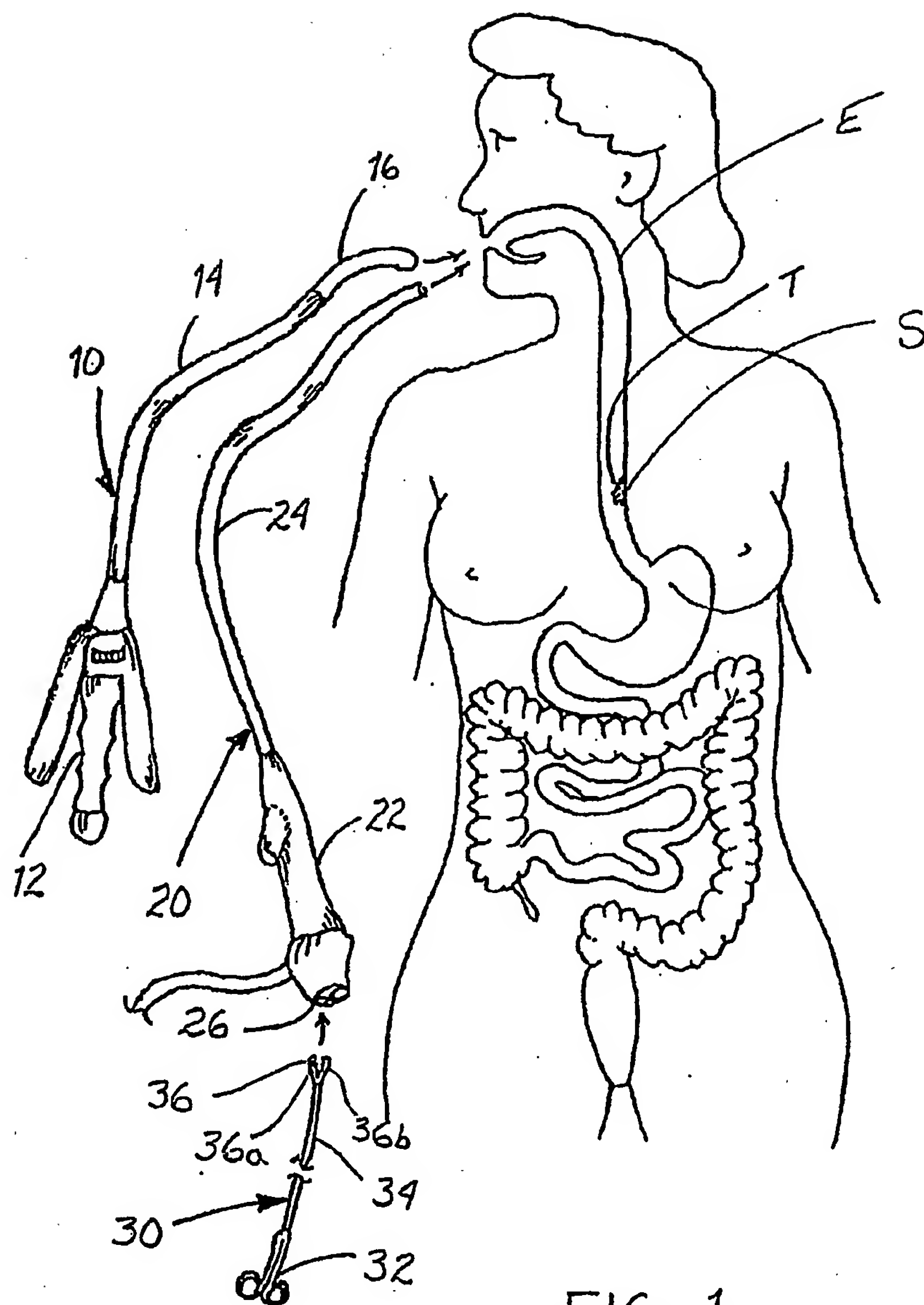


FIG. 1

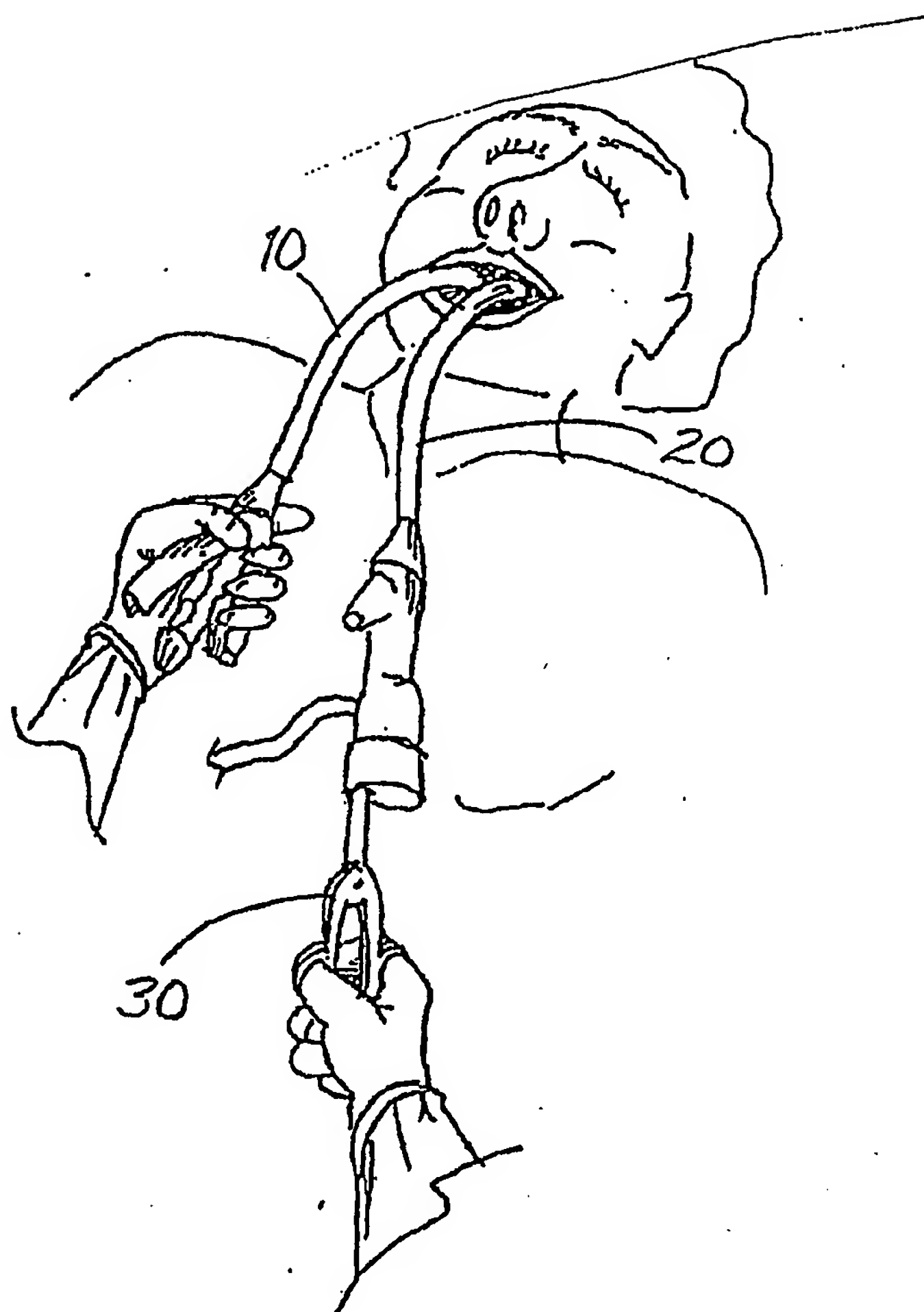
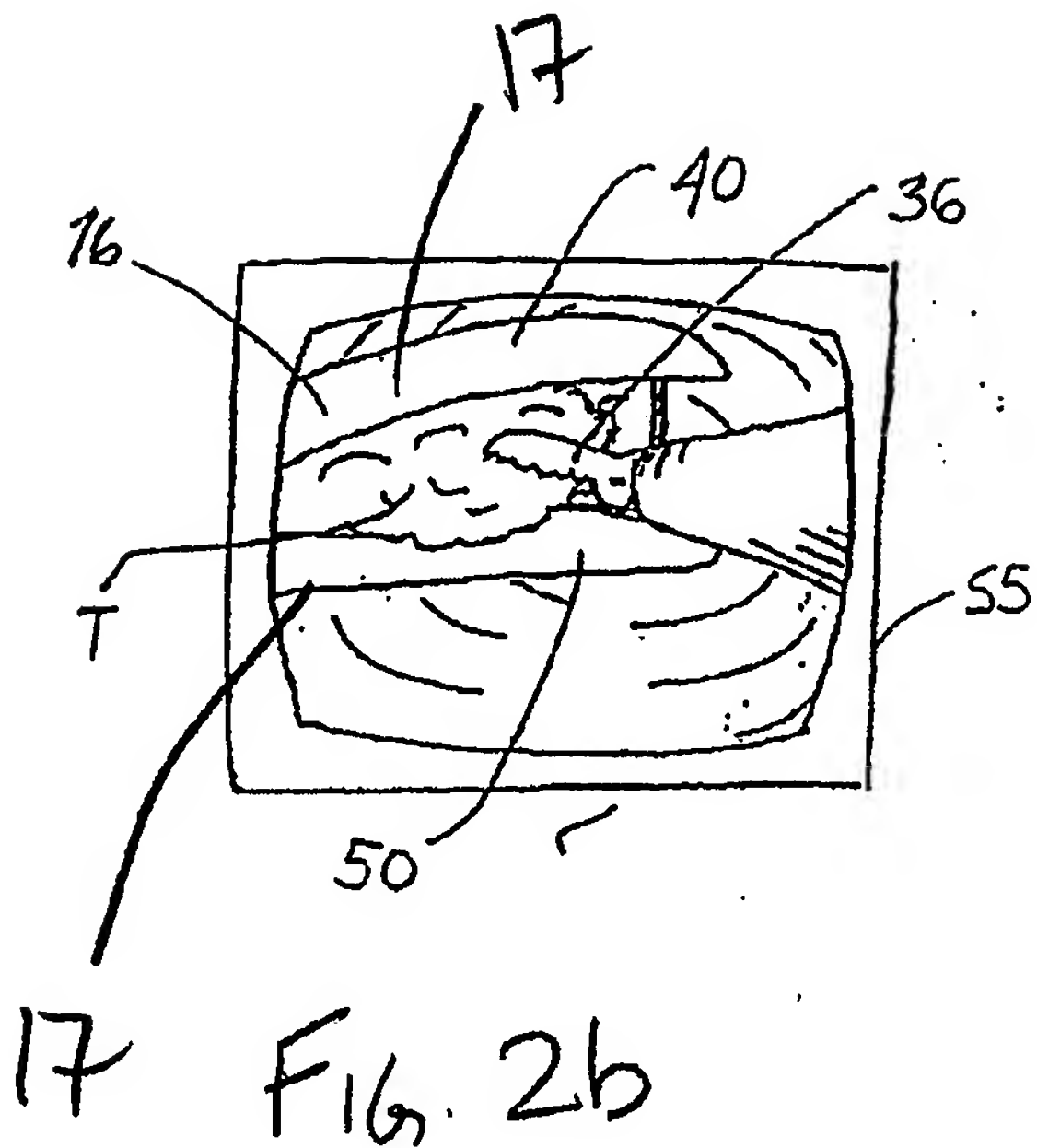


Fig. 2a



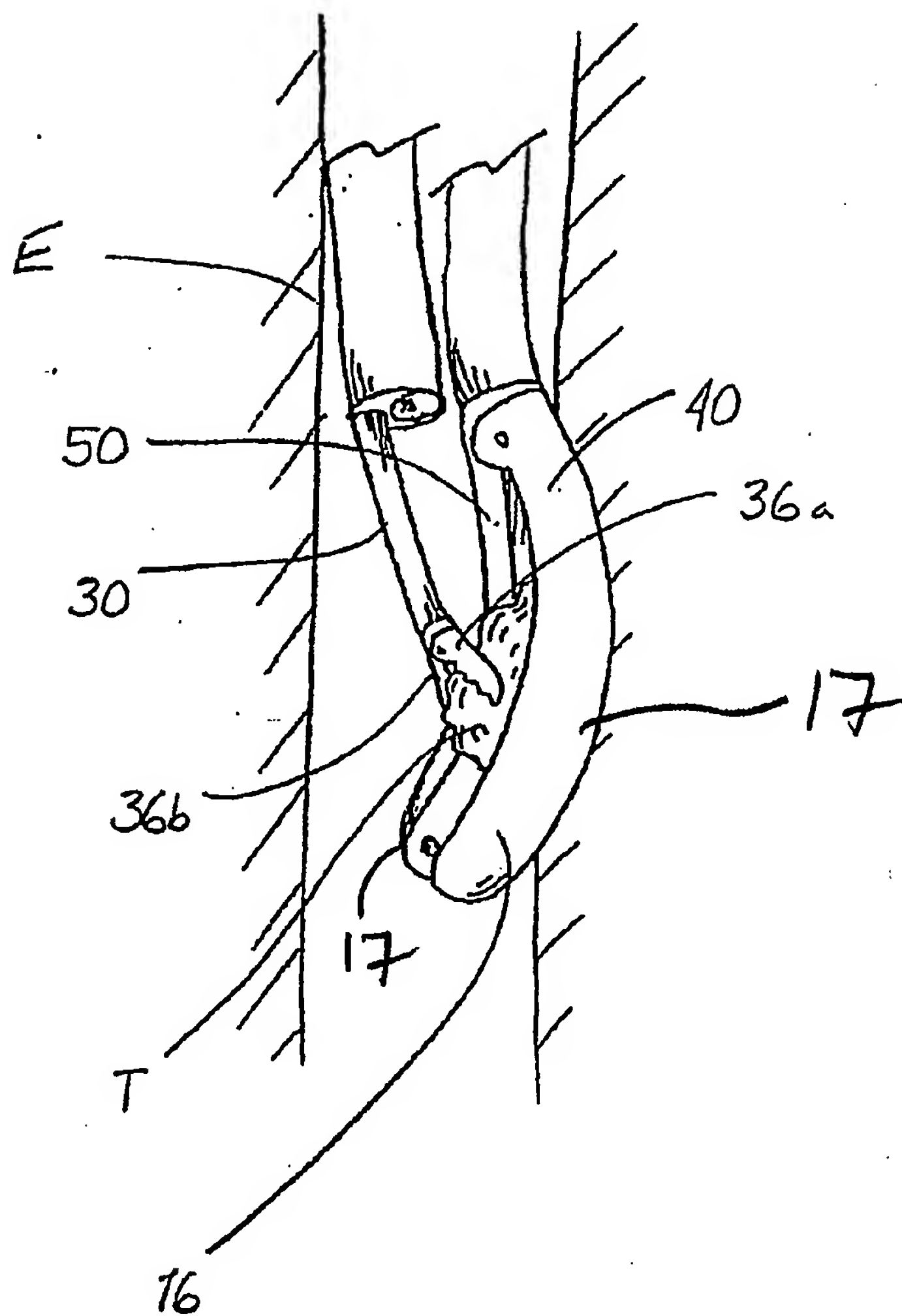
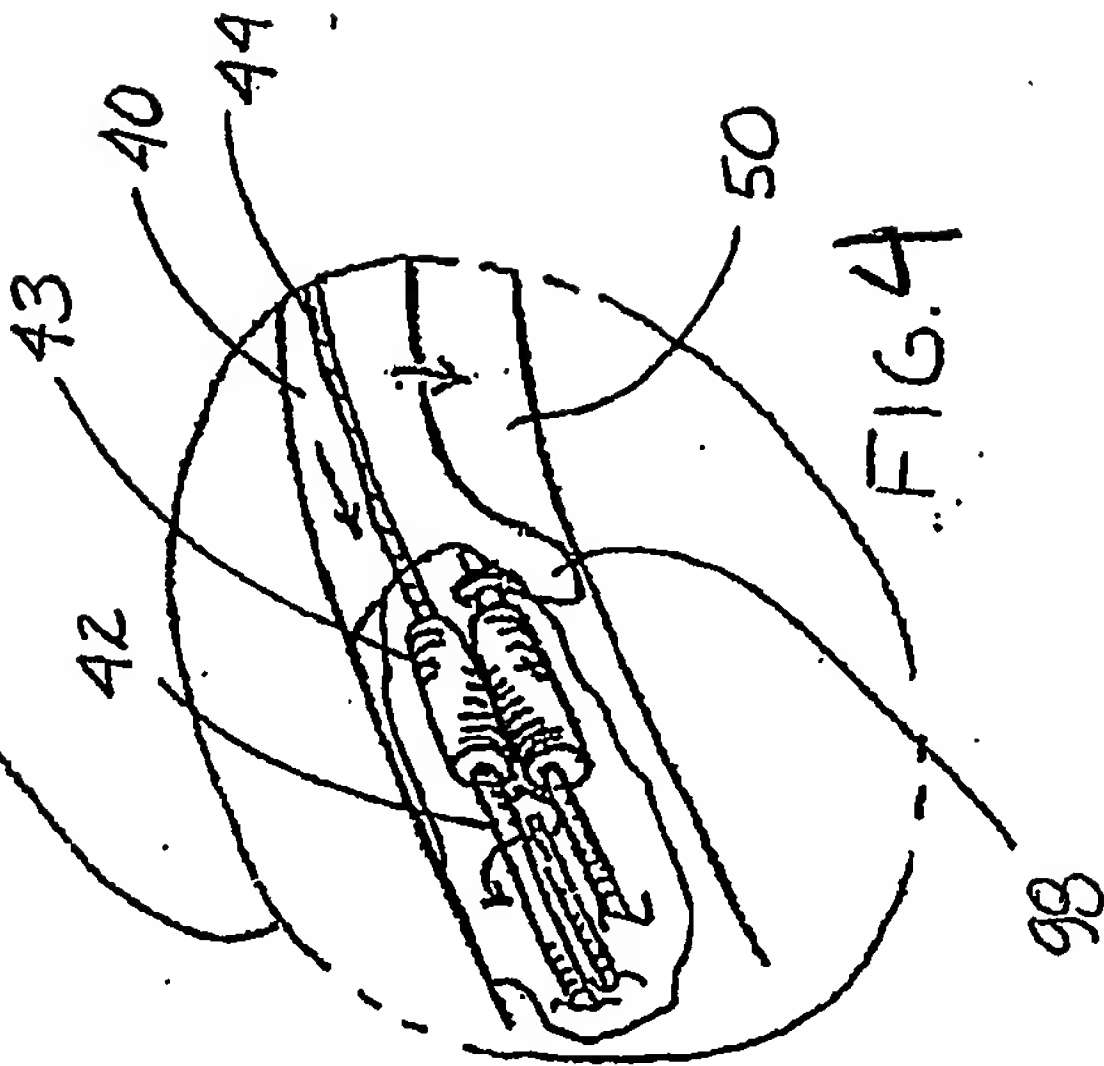
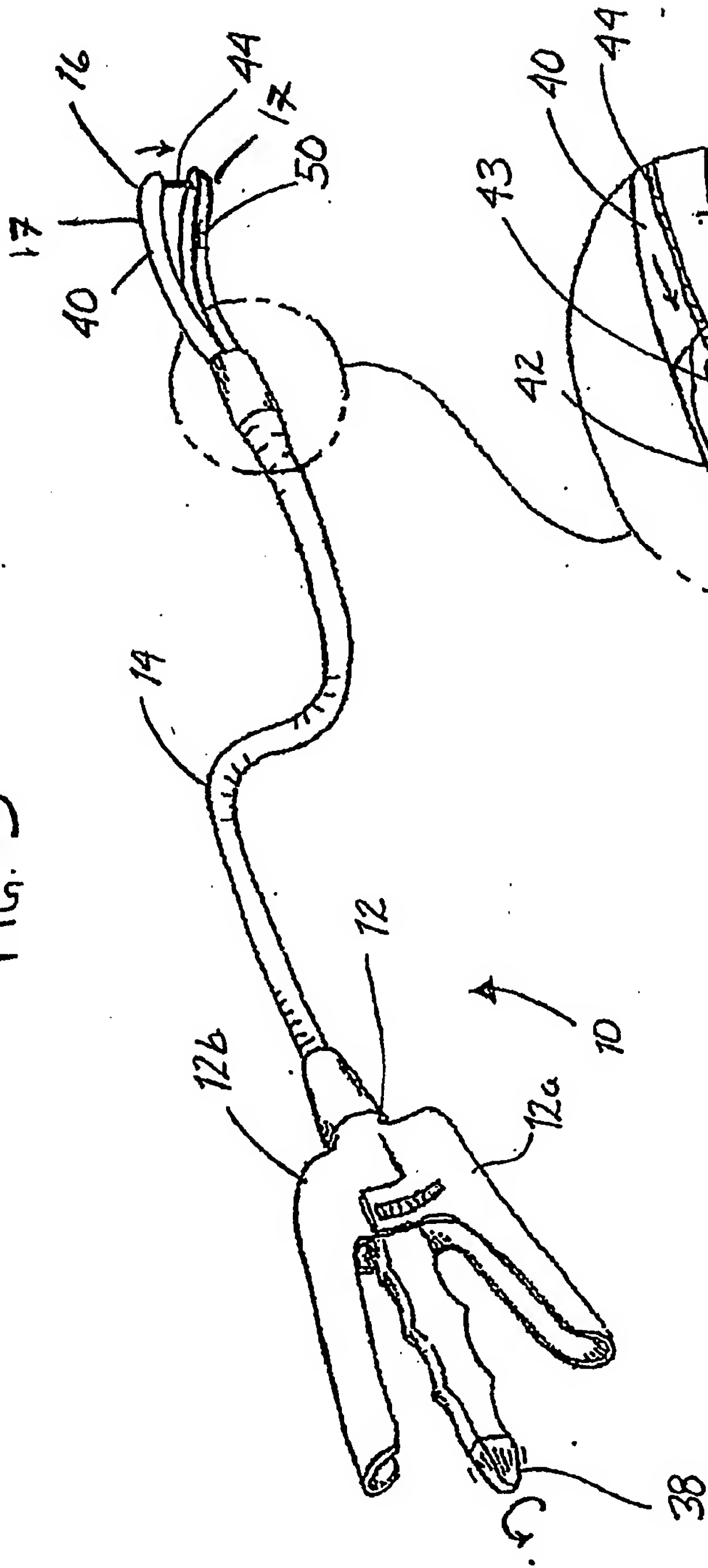
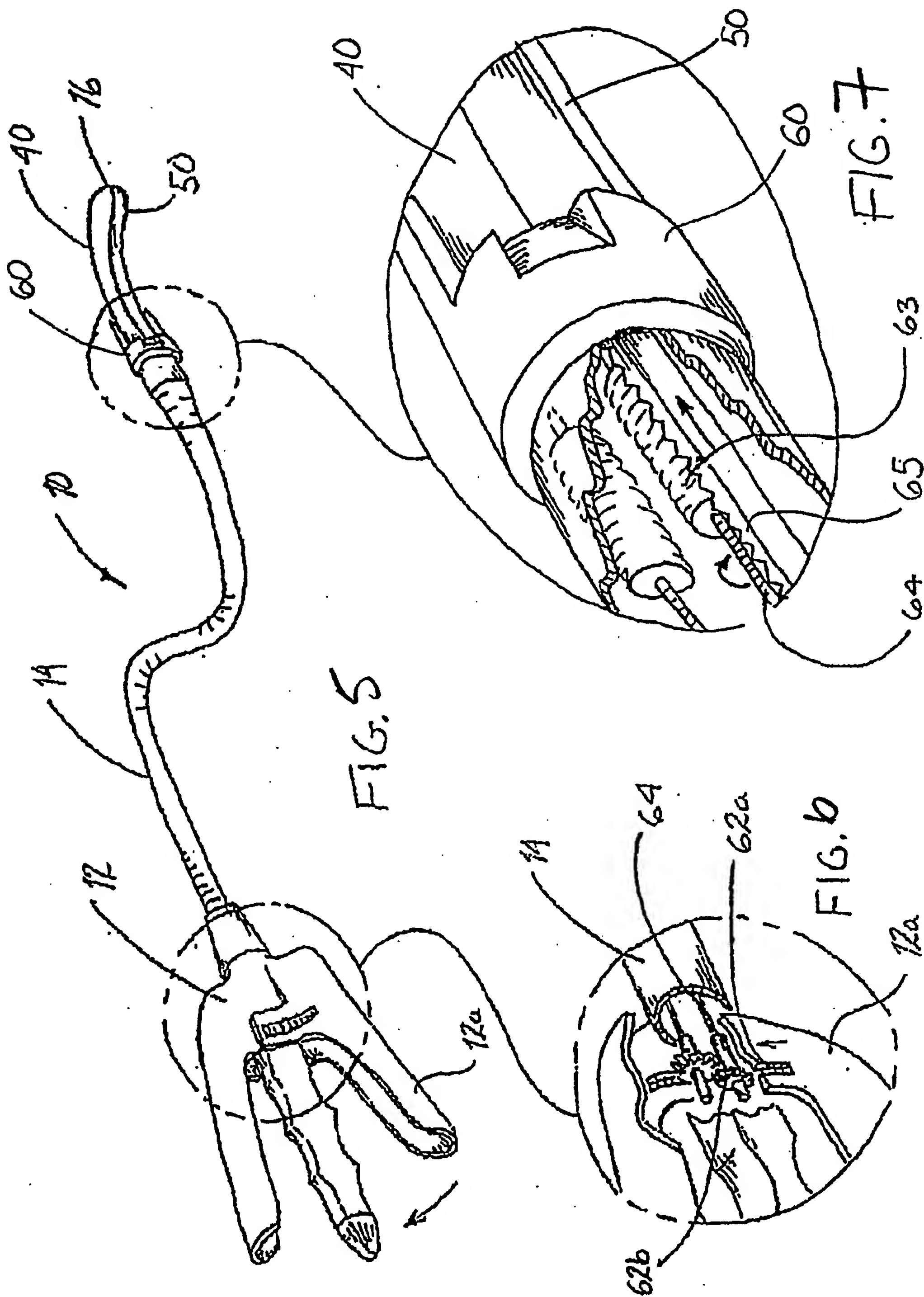


Fig. 2c

FIG. 3





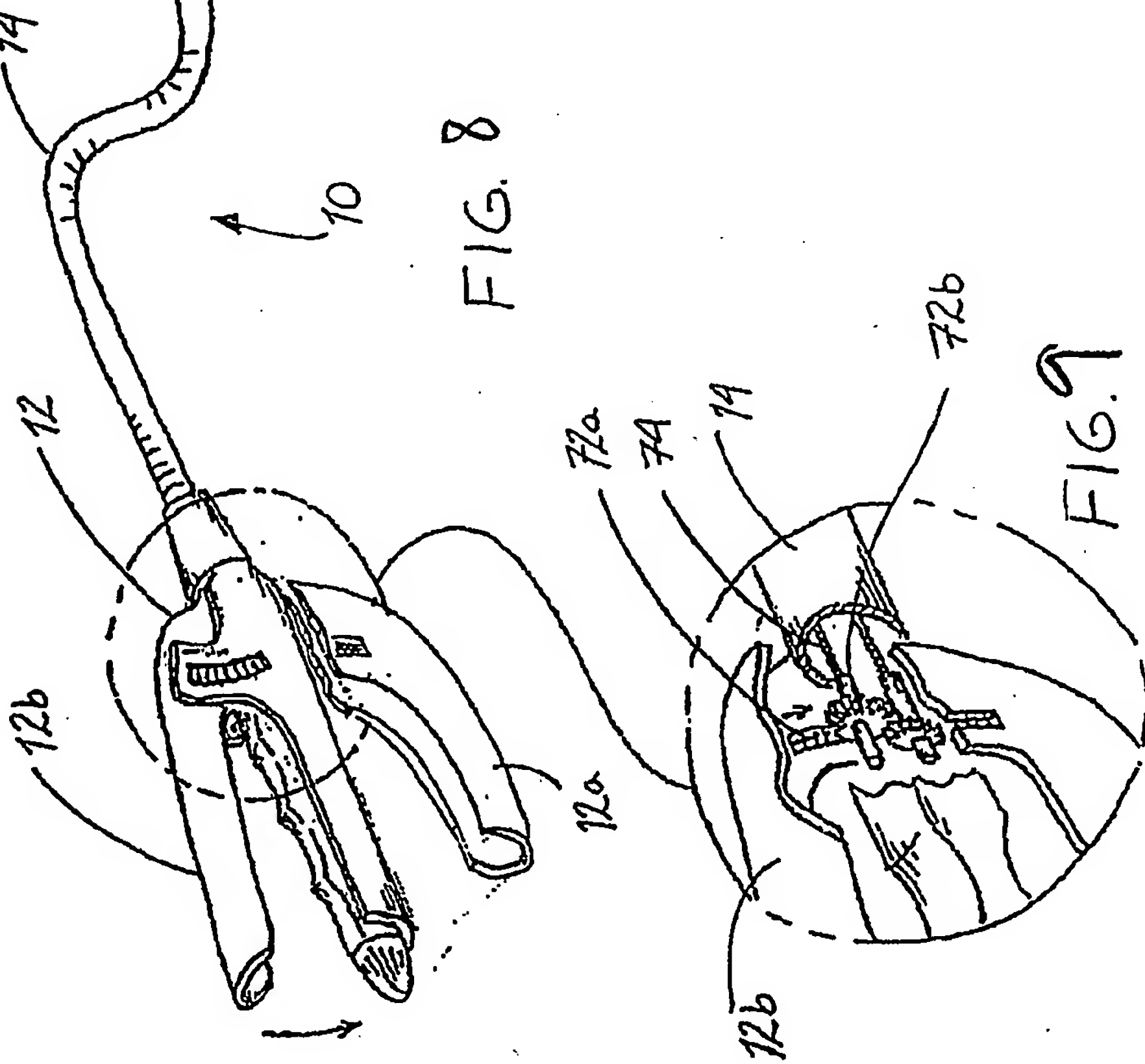
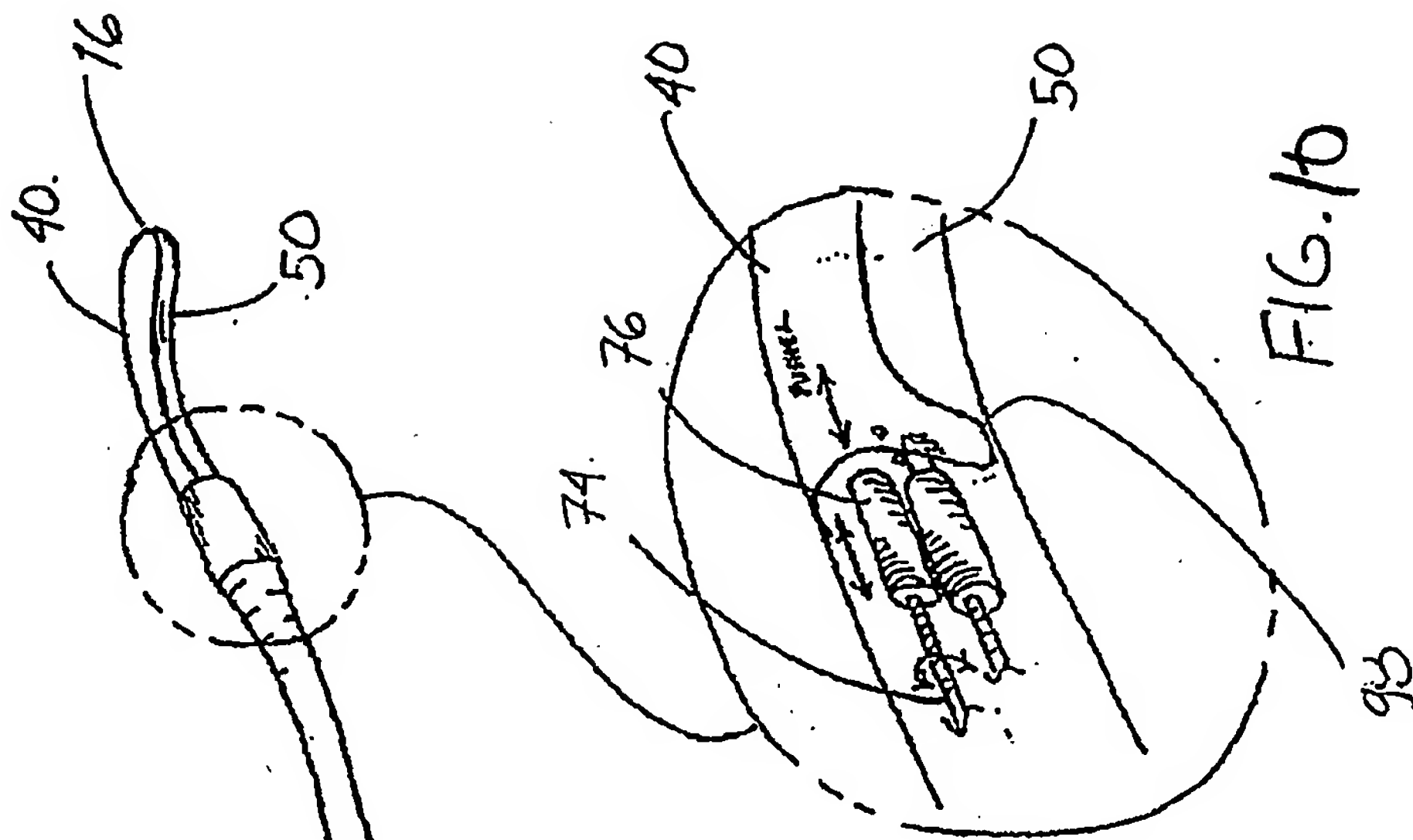


FIG. 8

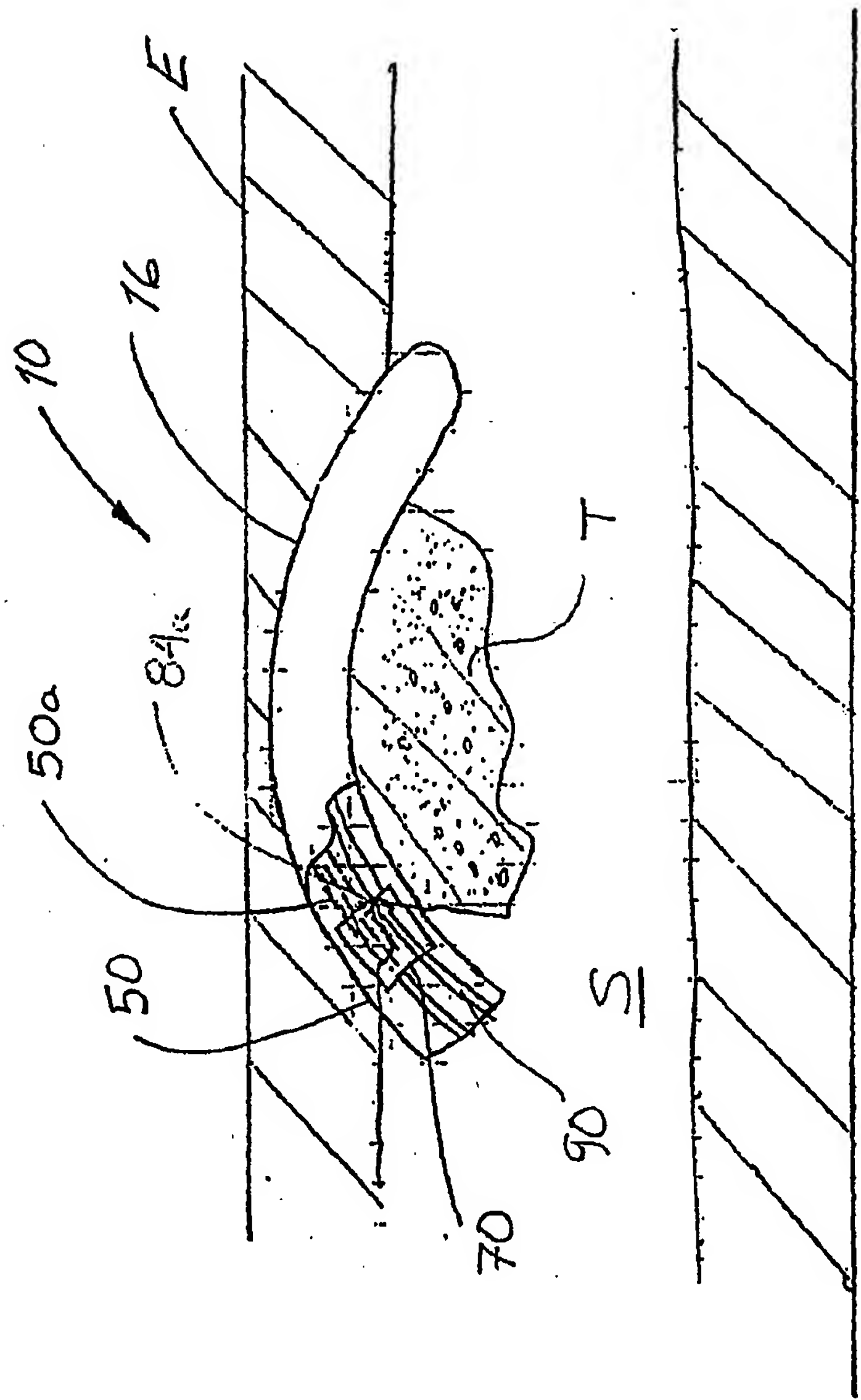
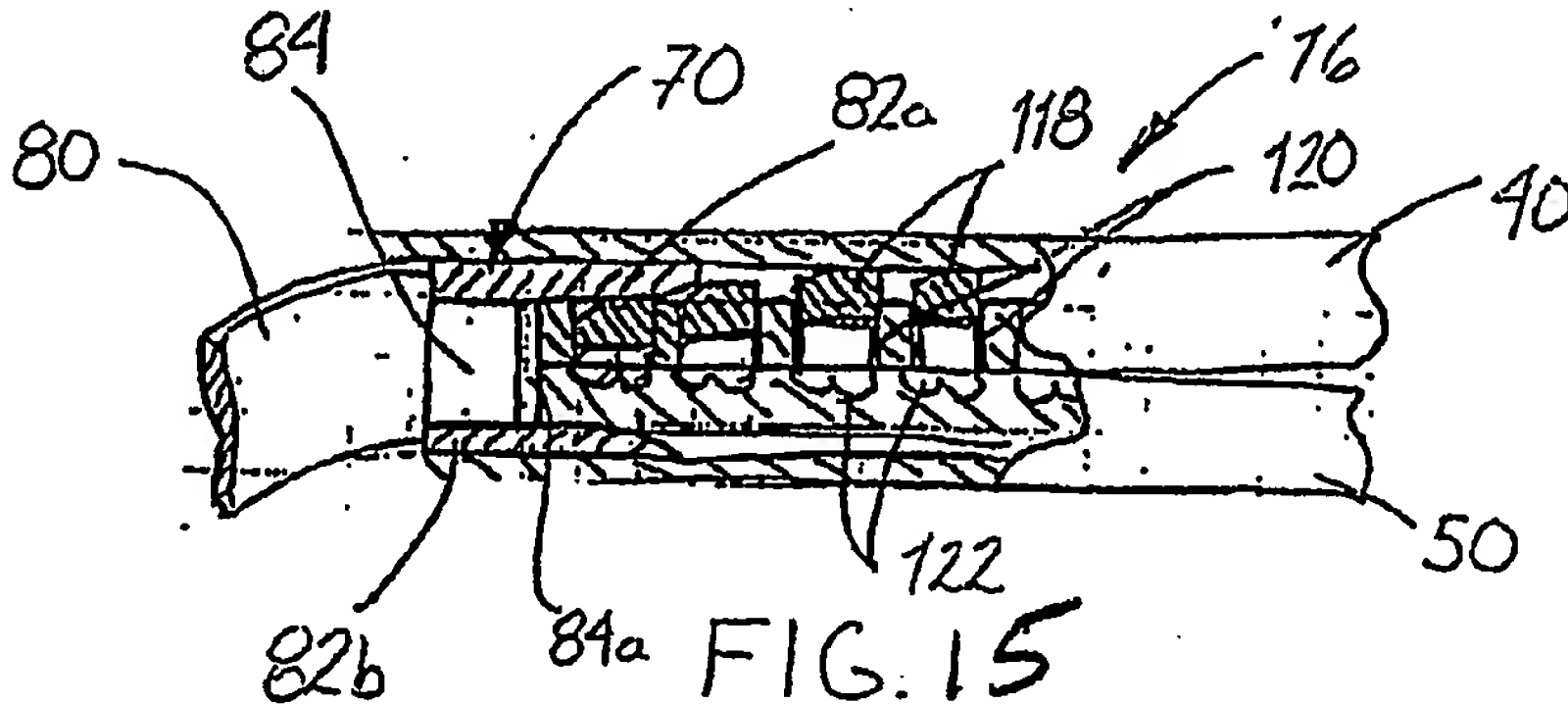
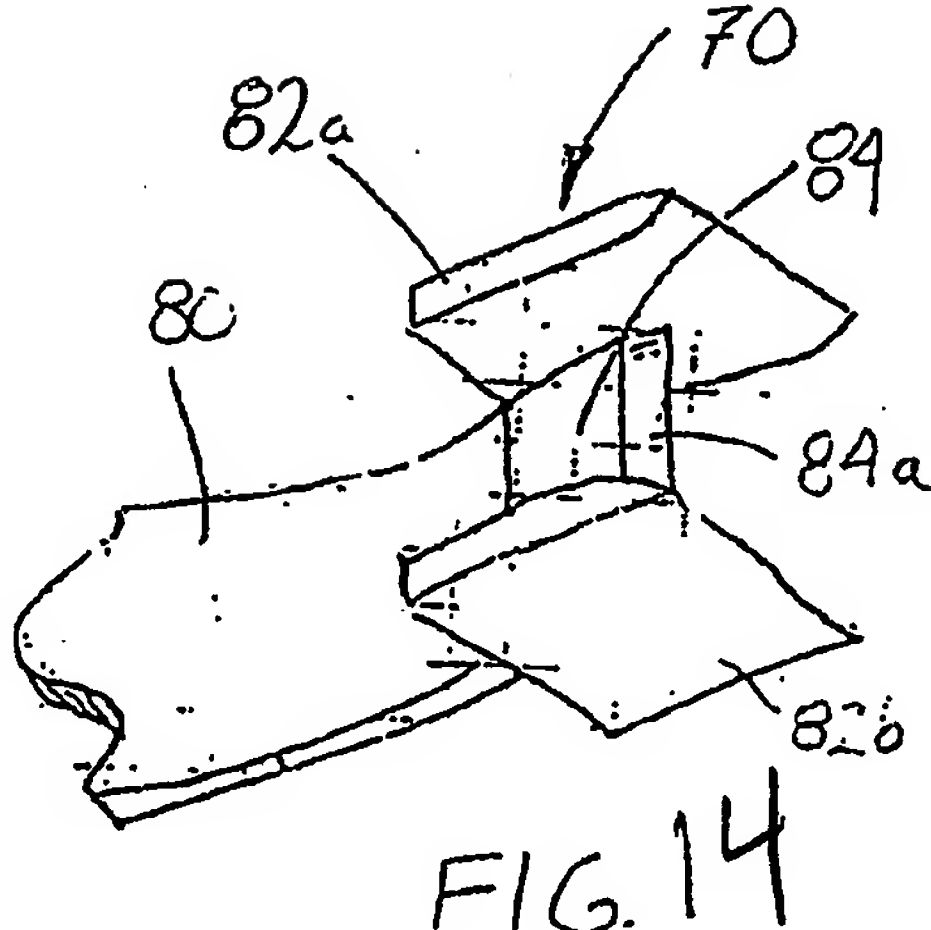
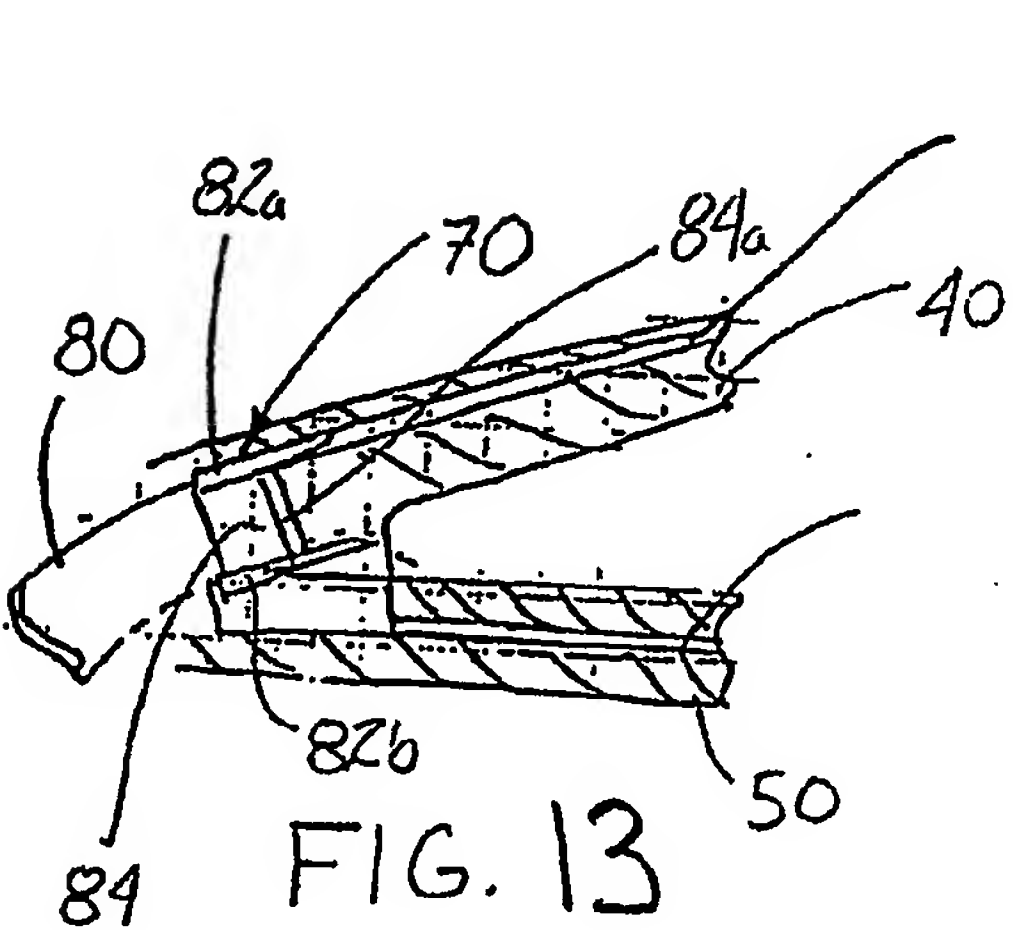
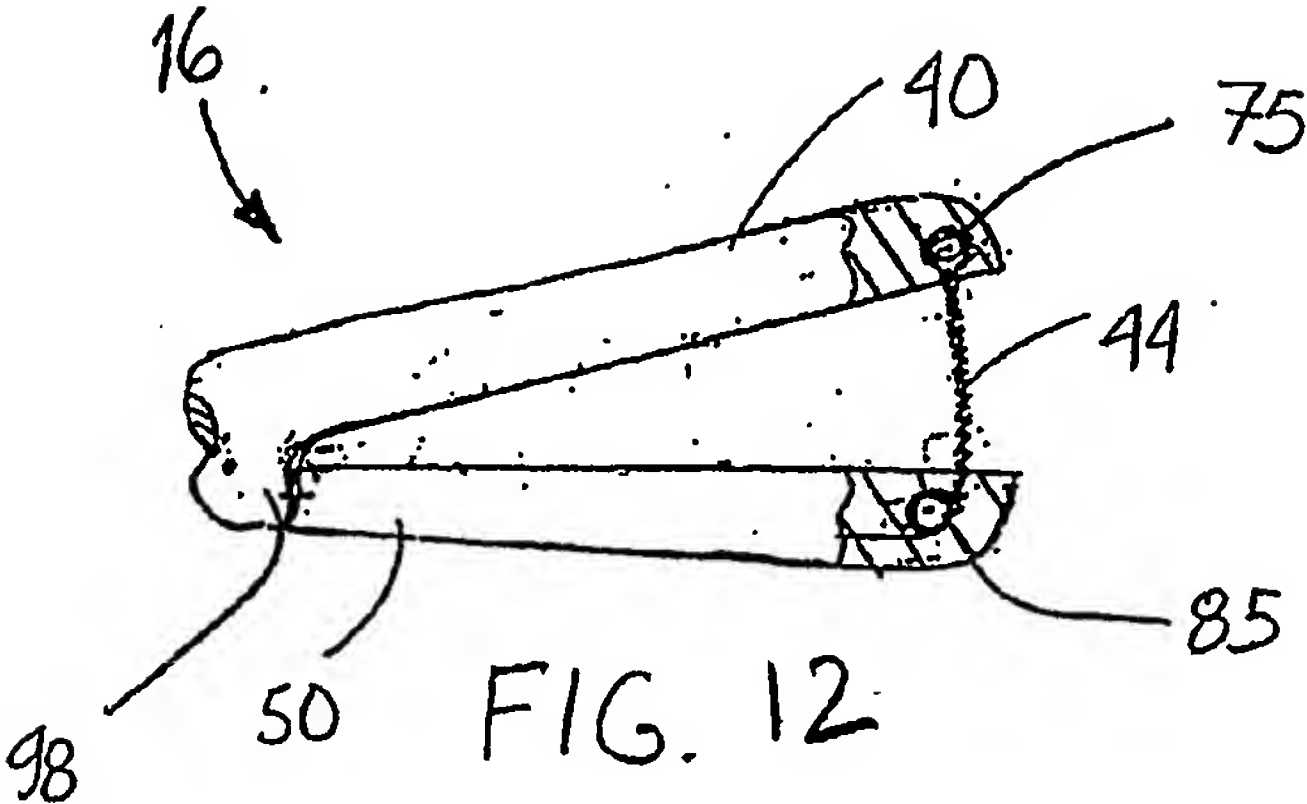
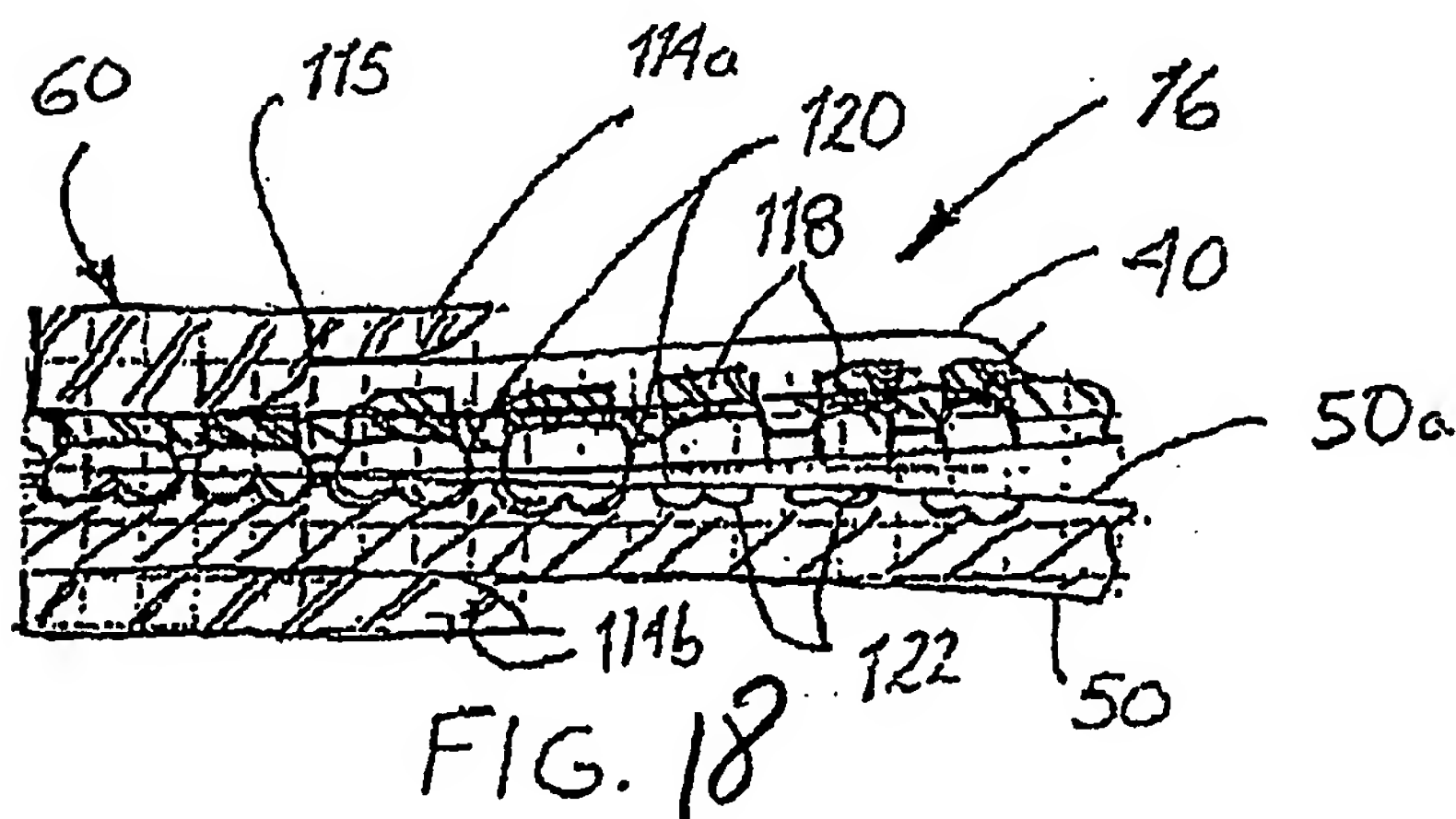
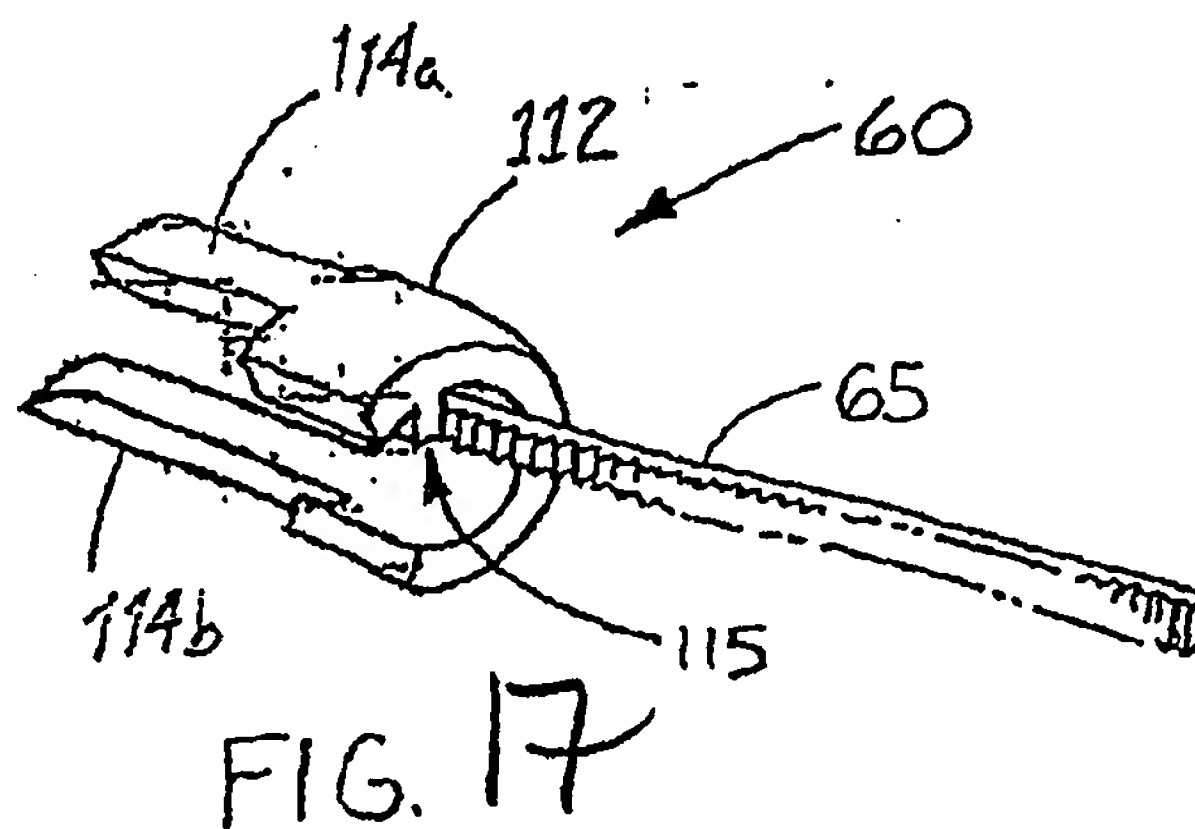
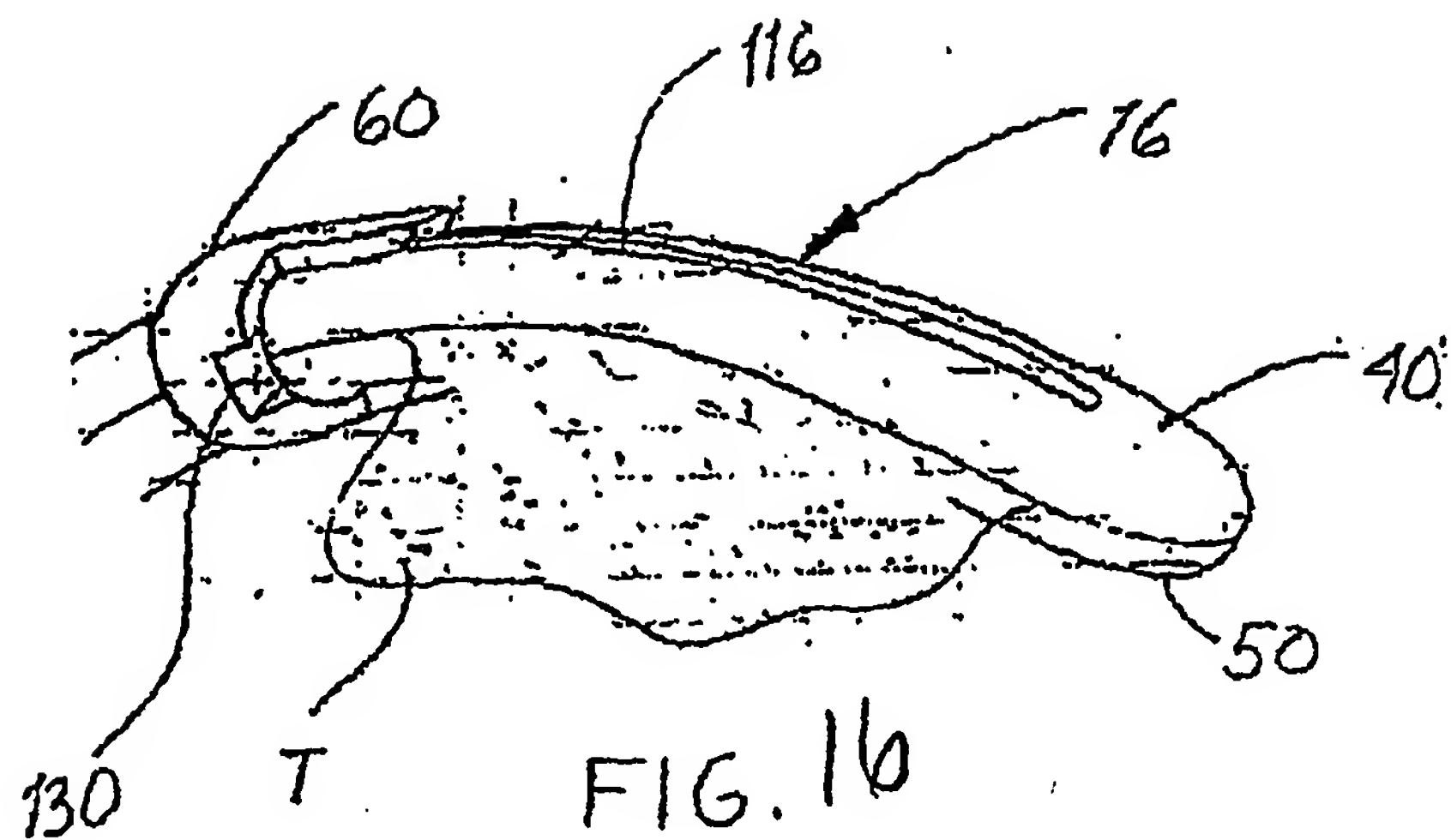


FIG. 11





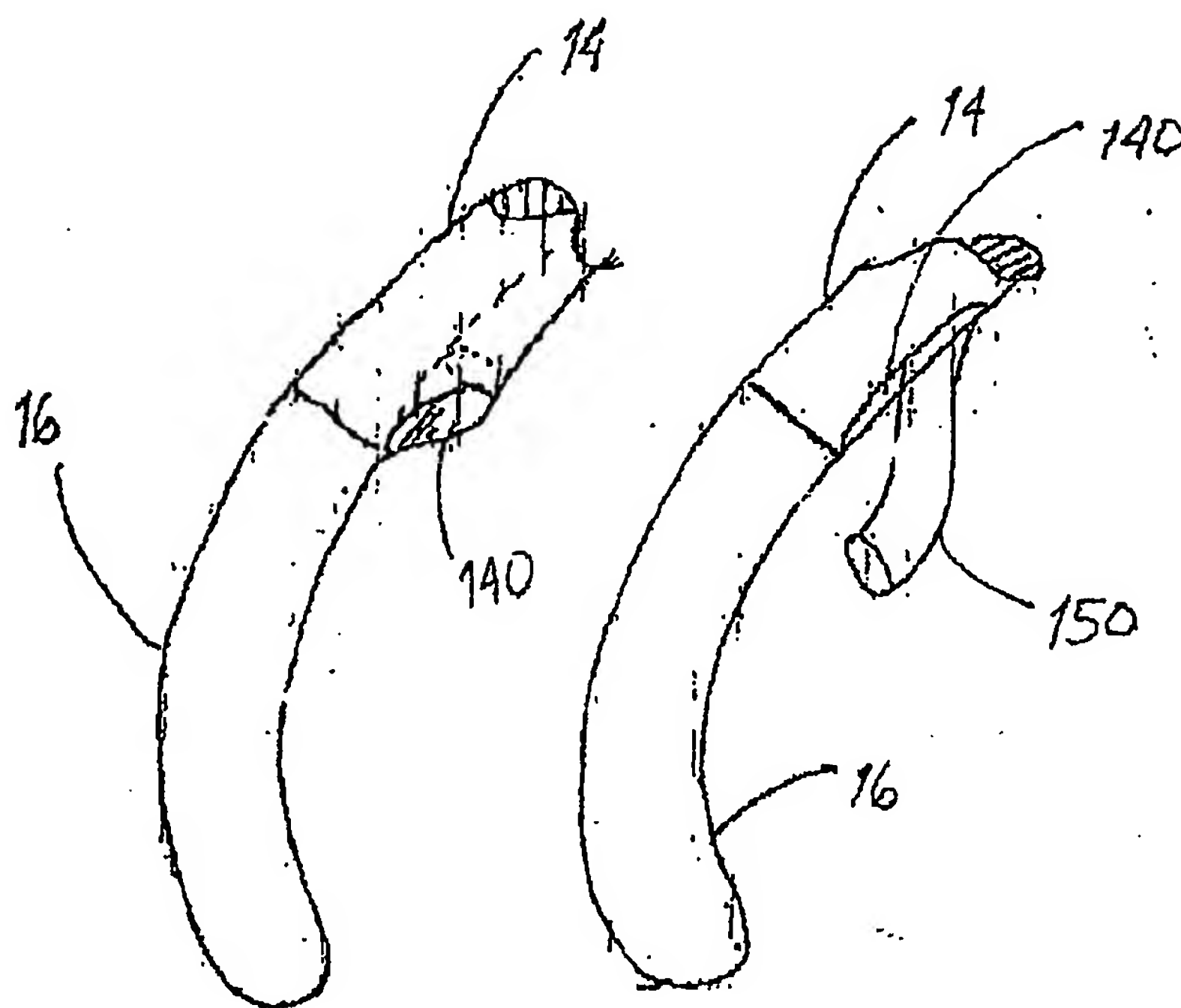
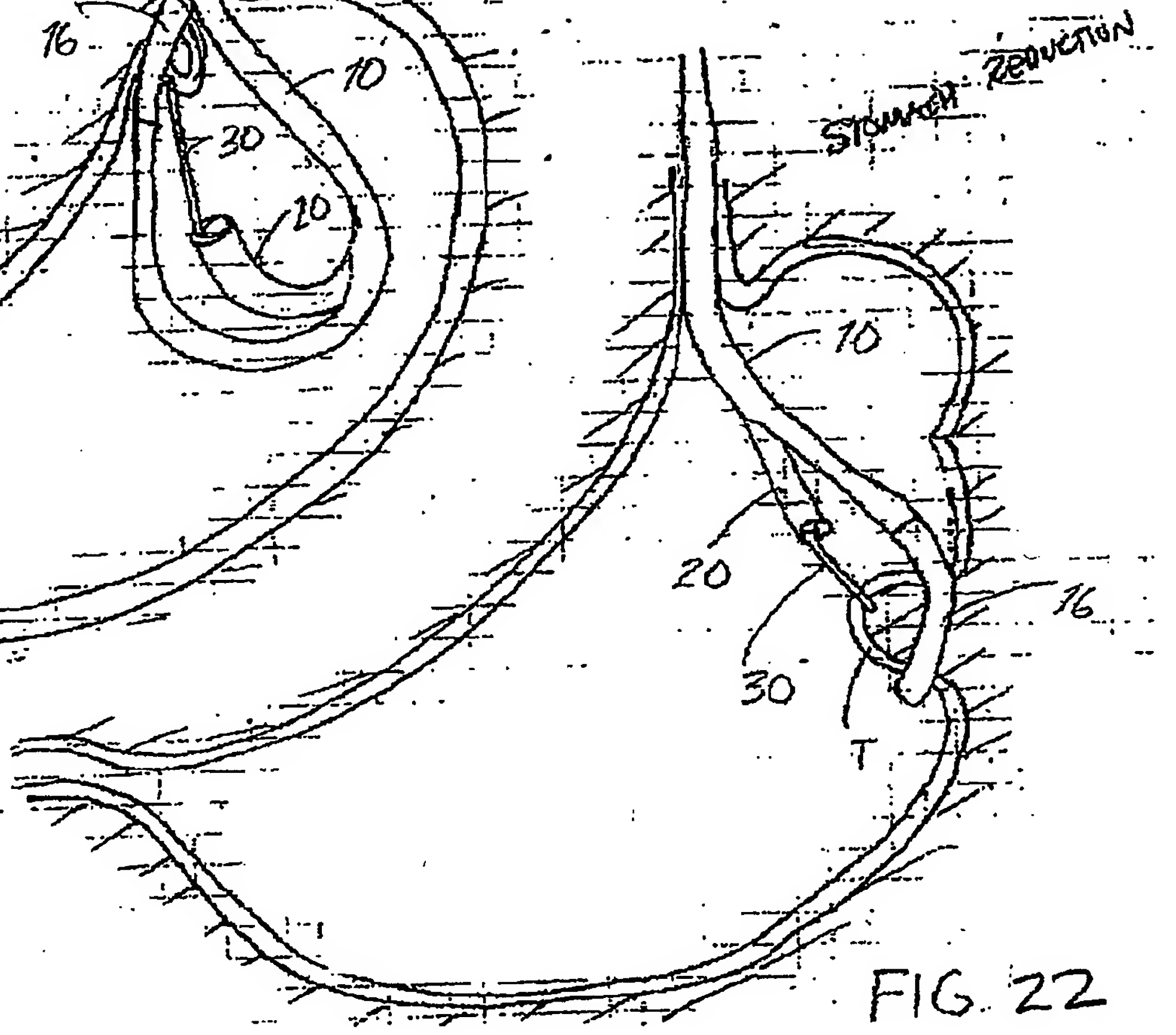
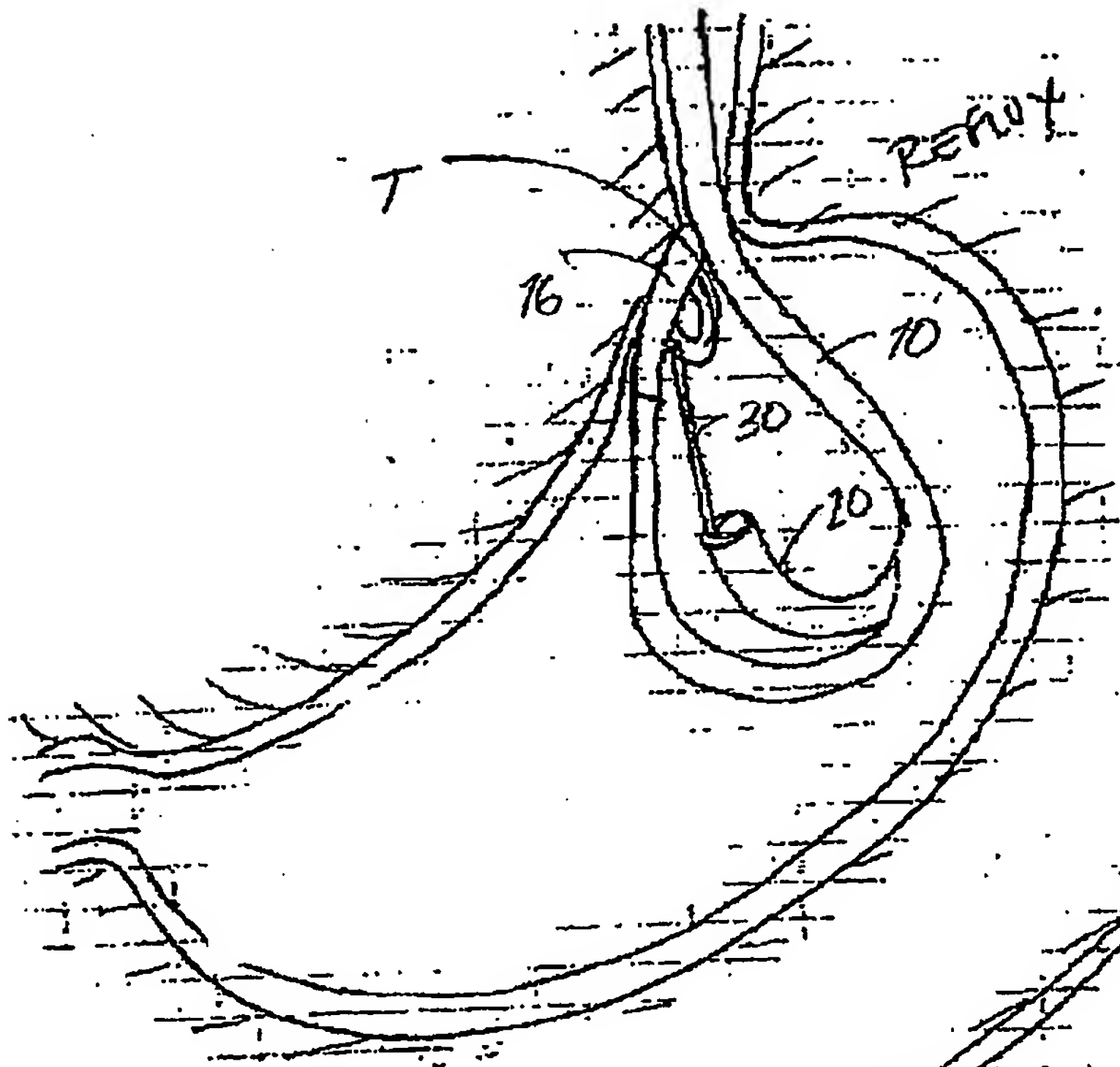


FIG. 19

FIG. 20



INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/03069

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/072

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 868 760 A (MCGUCKIN JR JAMES F) 9 February 1999 (1999-02-09) column 18, line 66 -column 24, line 25; figures 18-24	1-5
X	US 5 389 098 A (TSUKAGOSHI TSUYOSHI ET AL) 14 February 1995 (1995-02-14) cited in the application column 34, line 15 -column 35, line 7	1-5
A	US 5 657 921 A (YOUNG WAYNE P ET AL) 19 August 1997 (1997-08-19) column 3, line 56 -column 4, line 54	6-16
A	US 5 662 260 A (YOON INBAE) 2 September 1997 (1997-09-02) column 11, line 28 -column 12, line 37	6
	--- -/-	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

29 May 2002

Date of mailing of the international search report

24/06/2002

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INTERNATIONAL SEARCH REPORT

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PC1/US 02/03069

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US 5 667 517 A (HOOVEN MICHAEL DAWSON) 16 September 1997 (1997-09-16) column 4, line 43 - line 67 column 6, line 48 -column 7, line 34 -----</p>	1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 02/03069

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 17-20
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

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2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
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4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte

Application No

PCT/US 02/03069

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5868760	A	09-02-1999	AU 716048 B2	17-02-2000
			AU 4509796 A	03-07-1996
			CA 2206275 A1	20-06-1996
			CN 1175193 A	04-03-1998
			EP 0918486 A2	02-06-1999
			JP 11506943 T	22-06-1999
			WO 9618344 A2	20-06-1996
			US 6264086 B1	24-07-2001
US 5389098	A	14-02-1995	JP 5317323 A	03-12-1993
			JP 5317320 A	03-12-1993
			JP 5329167 A	14-12-1993
			JP 5337120 A	21-12-1993
			JP 5337119 A	21-12-1993
			JP 6030944 A	08-02-1994
			JP 6030945 A	08-02-1994
			US 5582611 A	10-12-1996
US 5657921	A	19-08-1997	US 5507426 A	16-04-1996
			AU 692572 B2	11-06-1998
			AU 2831995 A	15-02-1996
			EP 0699417 A1	06-03-1996
			JP 8173437 A	09-07-1996
US 5662260	A	02-09-1997	US 5551622 A	03-09-1996
			AU 700734 B2	14-01-1999
			AU 2914595 A	16-02-1996
			EP 0954243 A2	10-11-1999
			WO 9602279 A2	01-02-1996
			US 5833695 A	10-11-1998
			US 5655698 A	12-08-1997
			US 5662259 A	02-09-1997
US 5667517	A	16-09-1997	US 5383880 A	24-01-1995
			US 5518163 A	21-05-1996
			US 5518164 A	21-05-1996
			AT 192639 T	15-05-2000
			AU 670051 B2	04-07-1996
			AU 3117893 A	22-07-1993
			CA 2087221 A1	18-07-1993
			DE 69328576 D1	15-06-2000
			DE 69328576 T2	04-01-2001
			DK 552050 T3	07-08-2000
			EP 0552050 A2	21-07-1993
			ES 2146216 T3	01-08-2000
			GR 1001562 B	29-04-1994
			JP 6007357 A	18-01-1994
			PT 552050 T	31-08-2000
			US 5433721 A	18-07-1995

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